

K032408

OCT 15 2003



SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.  
1717 W. Collins Avenue  
Orange, California 92867  
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Colleen Boswell - Contact Person

Date Summary Prepared: August 2003

Device Name:

- Trade Name – Damon FT
- Common Name – Plastic Orthodontic Bracket
- Classification Name – Bracket, Plastic, Orthodontic, per 21 CFR § 872.5470

Devices for Which Substantial Equivalence is Claimed:

- Ormco Corporation, *Spirit MB*

Device Description:

The device is a polycarbonate orthodontic bracket which will encompass maxillary and mandibular brackets from second bicuspid to second bicuspid. The Damon FT appliance has both aesthetic and self-ligating qualities. The Damon FT bracket is designed to 1) increase patient comfort, with its increased corner radius, 2) enhance bracket placement, with its rhomboid design, and 3) improve overall bracket performance without changing treatment mechanics, with its metal archwire slot, rotation control similar to Damon 2 bracket, and compatibility with the Damon 2 bracket.

Intended Use of the Device:

The intended use of *Damon FT* is as a plastic orthodontic bracket that is designed for the movement of teeth during orthodontic treatment.

Substantial Equivalence:

*Damon FT* is substantially equivalent to other legally marketed devices in the United States. *Damon FT* functions in a manner similar to and is intended for the same use as the *Spirit MB* bracket marketed by Ormco Corporation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 15 2003

Mr. Colleen Boswell  
Director, Corporate Compliance  
Sybron Dental Specialties, Incorporated  
1717 West Collins Avenue  
Orange, California 92867

Re: K032408  
Trade/Device Name: Damon FT  
Regulation Number: 872.5470  
Regulation Name: Orthodontic Plastic Bracket  
Regulatory Class: II  
Product Code: DYW  
Dated: August 1, 2003  
Received: August 4, 2003

Dear Mr. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Section I - Indications for Use

Ver/ 3 - 4'24/96


Applicant: Ormco Corporation

510(k) Number (if known): K032408

Device Name: Damon FT

Indications For Use:

Damon FT is a polycarbonate bracket system intended to aid in the movement of patient's teeth during orthodontic treatment.

  
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(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices  
510(k) Number: K032408

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)  
(Optional Format 1-2-96)